Independent claims 1 and 12 describe a drug particle having an initial mass and a diffusional boundary layer having a volume. The ratio in question is defined as "the ratio of the initial mass of the drug particle to the volume of the diffusional boundary layer." (Claims 1 and 12) This ratio is further defined as "being such that the drug particle is solubilized to an extent greater than 0.001 milligram per milliliter." The ratio described in the claims is also detailed in the written description. In particular, Equation 2 (page 5, line 12) explicitly defines the relationship between the volume of the diffusional boundary layer (V_{BL}) and the mass of the drug particle (M_P):

$$M_P/C_{SAT} = V_{BL}$$

As is evident, Equation 2 also relates particle solubility (C_{SAT}) to boundary layer volume (V_{BL}) and particle mass (M_P). Thus, the terms used in claims 1 and 12 to describe a "ratio" are clearly defined in the instant specification. In view of these remarks, it is respectfully submitted that one of skill in the art would understand the ratio referred to in independent claims 1 and 12. It is therefore requested that the rejection of claims 1-14 under 35 U.S.C. 112, second paragraph, be withdrawn.

Remarks Directed to Rejection under 35 U.S.C. 102(b)

Claims 1, 2, 5, 6 and 8-14 were held to lack novelty under 35 U.S.C. 102(b) as being anticipated by Amidon et al. (US Patent 5,834,022).

In order for the cited reference to have anticipated Applicant's invention, the reference must teach every element of the claim. (MPEP, 7th Ed., revision 1, 2131) Independent claims 1 and 12 of the present invention teach that the ratio of the mass of the drug particle to the volume of the diffusional boundary layer solubilizing the drug particle to an extent greater than 0.001 milligram per milliliter.

Amidon et al. is cited as teaching a coating composition consisting essentially of gelatin and lecithin, having a drug disposed within the boundary layer. Amidon et al. is also cited as teaching increased dissolution of cyclosporin and griseofluvin by 20% and 40% respectively when used in the drug delivery system described in US Patent 5,834,022.

In contrast to the present claims, Amidon et al. does not teach the relationship between the mass of the drug particle and the volume of the diffusional boundary layer in solubilizing the drug particle taught in the present invention. The present specification teaches that the "size of the diffusional boundary layer can be controlled" and "the concentration of a particular surfactant used with a particular drug can be calculated." Thus, the ratio of drug particle mass and boundary layer volume and its relationship to solubility taught in the present specification "involves controlling the thickness of the diffusional boundary layer and controlling the concentration of the drug at the solid-liquid interface" in order to maintain the boundary layer "at a volume sufficient to solubilize substantially the entire drug particle." Amidon et al. nowhere teaches the above-detailed ratio and its role in drug release.

Further, the instant specification teaches that an inventive pharmaceutical delivery vehicle increases the "dissolution rate of water-insoluble pharmaceutical ingredients." (page 10, line 5) Referring to Figure 3 of the instant specification, it is shown that the rate of release of a pharmaceutical compound from an inventive delivery vehicle is greater than when bulk powder is used. Amidon et al. shows increased dissolution of various formulations compared to bulk powders which do not show measurable dissolution over 2 hours. (Figures 2-7) However, Amidon et al. nowhere shows increased rate of release of a drug compared to a bulk powder which <u>does</u> solubilize to a measurable time over 2 hours as does the present inventive vehicle (Figure 3).

On the basis of these arguments, it is submitted that claims 1, 2, 5, 6 and 8-14 are not anticipated under 35 U.S.C. 102(b) by Amidon et al. Therefore, it is respectfully requested that the rejection of claims 1, 2, 5, 6 and 8-14 as anticipated by Amidon et al. be withdrawn.

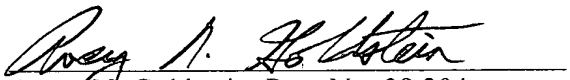
Remarks Directed to Rejection under 35 U.S.C. 103(a)

Claims 3, 4 and 7 were held to be unpatentable under 35 U.S.C. 103(a) for being obvious over Amidon et al. (US Patent 5,834,022) in view of Woo (US Patent 5,589,455) and Gennaro et al. (Remington's Pharmaceutical Sciences, 18th ed., 1990, page 1662-1664). In view of the Applicant's belief as to the allowability of the independent claims, dependent claims 3, 4 and 7 are likewise submitted to be allowable. It is respectfully requested that the rejection under 35 U.S.C. 103(a) be withdrawn.

Summary

Claims 1-20 are the pending claims in this application. Each claim is believed to be in proper form and directed to allowable and patentable subject matter. Entry of this response and allowance of the claims is requested.

Respectfully submitted,



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Janice R. Kuehn

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